Quality standards

Edition: BP 2025 (Ph. Eur. 11.6 update)

Ergocalciferol Injection

General Notices

Action and use

Vitamin D analogue (Vitamin D₂).

DEFINITION

Ergocalciferol Injection is a sterile solution of Ergocalciferol in Ethyl Oleate.

The injection complies with the requirements stated under Parenteral Preparations and with the following requirements.

Content of ergocalciferol, C28H44O

90.0 to 110.0% of the stated amount.

CHARACTERISTICS

A colourless to pale yellow, oily liquid.

IDENTIFICATION

To 1 mL of a 0.2% v/v solution of the injection in <u>ethanol-free chloroform</u> add 9 mL of <u>antimony trichloride solution</u>. The <u>light absorption</u> of the resulting solution, <u>Appendix II B</u>, exhibits a maximum at 500 nm.

ASSAY

Carry out the following procedure in subdued light. Dilute 0.1 g of the injection to 50 mL with dry 1,2-dichloroethane that has been purified by passing it through a column of silica gel. To 1 mL of this solution add rapidly 9 mL of antimony trichloride in dichloroethane solution and measure the absorbance of the solution at 500 and 550 nm, Appendix II B, 90 to 120 seconds after adding the reagent. Repeat the operation using 1 mL of a 0.002% w/v solution of ergocalciferol BPCRS in the dry, purified 1,2-dichloroethane, beginning at the words 'add rapidly 9 mL of antimony trichloride solution...'. Calculate the result of the assay from the difference between the absorbances at 500 and 550 nm and using the declared content of C₂₈H₄₄O in ergocalciferol BPCRS. Calculate the percentage w/v of ergocalciferol taking 0.87 g as the value of the weight per mL of the injection.

STORAGE

Ergocalciferol Injection should be protected from light.

https://nhathuocngocanh.com/bp/

LABELLING

The label states (1) that the preparation is for intramuscular use only; (2) the equivalent number of IU (units) of antirachitic activity (vitamin D) in 1 mL.

Each µg of ergocalciferol is equivalent to 40 IU of antirachitic activity (vitamin D).

When calciferol injection is prescribed or demanded, <u>Colecalciferol Injection</u> or Ergocalciferol Injection shall be dispensed or supplied.